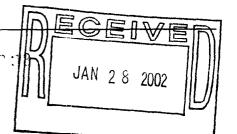


Whole Food Supplements -

November 15, 2001



The Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C. Street S.W. Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- 1. Saw palmetto liposterolic extract in pumpkin seed and soybean oils supports the male reproductive system, particularly the urinary tract and prostate gland.
- 2. It eases occasional smooth muscle spasms and helps support proper urine flow.

These statements are made for a dietary supplement containing saw palmetto liposterolic extract, free fatty acids, glycerides, and sterols. Other ingredients include pumpkin seed oil, soya oil, gelatin, and glycerol. The name of the product is Serenoa Complex.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden

Standard Process Inc.

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